DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 17, 2015

Guangzhou Finecure Medical Equipment Co., Ltd
% Field Fu
Shenzhen Joyantech Consulting Co., Ltd.
4th Floor, Jinhui Building, Nanhai Blvd.
Nanshan District
Shenzhen, Guangdong
China

Re: K142369
Trade/Device Name: Urinary Incontinence System
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: May 4, 2015
Received: May 15, 2015

Dear Field Fu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142369

Device Name
Urinary Incontinence System

Indications for Use *(Describe)*
The Urinary Incontinence System with various treatment modalities is intended to be used by males and females for muscle contraction in the treatment of stress incontinence, urge incontinence, and mixed incontinence.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 05 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR§807.92

The assigned 510(k) number is: K142369 (applicant leave blank)

Submission Date: May 7, 2015

Submitter: Guangzhou Finecure Medical Equipment Co., Ltd.
Address: F19, No.1 Kesheng Road, Baiyun Torch Building, No.1633 Beitai Road, Baiyun District, Guangzhou, CHINA.

***Submitter Contact*:** Shenzhen Joyantech Consulting Co., Ltd.
4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China.
Contact person: Mr. Field.Fu
E-Mail: cefda13485@163.com

***Manufacturing Site*:** Guangzhou Finecure Medical Equipment Co., Ltd.
Address: F19, No.1 Kesheng Road, Baiyun Torch Building, No.1633 Beitai Road, Baiyun District, Guangzhou, CHINA.

Device Name: Urinary Incontinence System

Common Name: Pelvic floor muscle stimulator

Classification Name: Nonimplanted electrical continence device

Regulation: 21 CFR §876.5320

Product Code: KPI

Type/Model of the device P3-9632E1 and P3-9632E2

Substantially Equivalent Devices: The Finecure Urinary Incontinence System is substantially equivalent to: the InControl InTone (K110179) and the I touch Sure (K103698).

Intended Use Indications for Use:	The Urinary Incontinence System with various treatment modalities is intended to be used by males and females for muscle contraction in the treatment of stress incontinence, urge incontinence, and mixed incontinence.
Device Description:	The Finecure Urinary Incontinence System is a non-implanted, electrical, pelvic floor muscle stimulator. It is intended to strengthen the pelvic floor muscles by electrical stimulation in the treatment for urinary incontinence. The system has several preset modes that correspond to different conditions associated with urinary incontinence. The Urinary Incontinence System can be used in the clinical setting and the home care environment. The System is composed of enclosure, display screen, PCB, rotary switch, and other electronic components. The system is to be used with pelvic floor probes and anorectal probes.
Technology Comparison to predicate device	The Finecure Urinary Incontinence System is employ the same technological characteristics compare to InControl InTone (K110179) and Itouch Sure (K103698) in the following table for determine the device whether substantially equivalent to the predicate devices.

Equivalence Comparison to the Predicate

	Finecure Urinary Incontinence System（new device)	**InControl InTone K110179**	**Itouch Sure K103698**	**Comparison**
Intended use & Indications for Use	The Urinary Incontinence System with various treatment modalities is intended to be used by males and females for muscle contraction in the treatment of stress incontinence, urge incontinence, and mixed incontinence.	The InControl device is non-implantedelectrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrus or muscle through reflexive mechanisms. The biofeedback feature can be used for muscle	The Itouch Sure is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women. The intended use and indications for use of the new device are the same as those of the predicate devices.	Similar[1]

	Finecure Urinary Incontinence System（new device)	InControl InTone K110179	Itouch Sure K103698	Compariso n
		re-education purposes.		
Power Source	6LR61/AM9V Alkalescent battery	4/5 AA nickel metal hydride battery	2 ×1.5AA	Equivalent
Output voltage	Adjustable, from 0～60V (500 ohm load).	50Vdc（500 ohm）	0～45V (500 ohm load).	Different[2]
Output current	Max Output current（500 Ohm) 120mA	Max Output current（500 Ohm） 100mA	Max Output current（500 Ohm） 90mA	Identical
Maximum Phase Charge, (mC)	36uC@500Ω	50uC@500Ω	unknown	Equivalent
Maximum Current Density	7.64mA/cm2 , for vaginal probe; 16.3 mA/cm2, fro anal probe.	4.7mA/cm2	unknown	Different[3]
Maximum Average Power Density	Pre2, 2.14mW/ cm2; Pre4, 14.6mW/ cm2 ; Pre5, 1.96mW/ cm2 ; Pre7, 9.78mW/ cm2	14.3mW/cm2@500Ω	unknown	Equivalent

	Finecure Urinary Incontinence System（new device)	**InControl InTone K110179**	**Itouch Sure K103698**	**Comparison**
Electrode Surface Area	For vaginal probe: 7.85×2=15.7 cm^2 For Anal probe: 3.68×2=7.36 cm^2	10.5 cm^2 x2	unknown	Equivalent
Number of output channels	2 channels	1 channel	unknown	Different[4]
Waveform	Dual phasic, rectangular pulse.	Dual phasic, rectangular pulses	Dual phasic, rectangular pulses	Same
Session Duration (min)	**Mode: Time(min)** PFS-Pre2, 0min/20min; (Pelvic floor muscle contraction) PFS-Pre4, 0min/20min; (Stress incontinence) PFS-Pre5, 0min/32min; (Urge incontinence)	12 mins	Continuous/15/30 min	Equivalent: For Pre2, Pre4, Pre7, the duration is within the predicate K103698; For Pre5, the duration is close to the predicate K103698.

	Finecure Urinary Incontinence System（new device)	**InControl InTone K110179**	**Itouch Sure K103698**	**Compariso n**
	PFS-Pre7 0min/20min. (Mixed incontinence)			
Pulse Rate (PR, Hz)	**Mode:** PFS-Pre2 （muscle contraction）35Hz; PFS-Pre4(Stress UI):50Hz; PFS-Pre5(Urge UI):10Hz； PFS-Pre7 (Mixed UI): 50Hz	50Hz	10/20/35/50Hz	Equivalent: For Pre2, Pre4, Pre5: the frequency is respectively same as the predicate k103698; For Pre7, the frequency same as the predicate k110179;

	Finecure Urinary Incontinence System（new device)	**InControl InTone K110179**	**Itouch Sure K103698**	**Compariso n**
Pulse Width	**Mode: PW(μS)** PFS-Pre2(muscle contraction) : 250us; PFS-Pre4(Stress UI):300us; PFS-Pre5(Urge UI）:200us; PFS-Pre7 (Mixed):200us;	200μS/phase	200/250/300/phase	Equivalent
Time ON and OFF	**Mode: ON and OFF time** PFS-Pre2, ON:15secs, OFF:5secs ; PFS-Pre4,ON:10secs, OFF:10secs; PFS-Pre5, ON:10secs, OFF:10secs; PFS-Pre7 ON:10secs, OFF:10secs;	ON:20secs OFF:10secs	unknown	Equivalent (Within range)
Applicable Patients	Male and female	Female	Female	Equivalent
Regulated current of voltage?	Regulated voltage	Regulated voltage	Regulated voltage	Same
Firmware controlled?	Yes	Yes	Yes	Same
Automatic Shut Off?	Yes	Yes	Yes	Same

Testing Summary

The testing for Urinary Incontinence System included performance, software, electrical safety, EMC, biocompatibility and bench. Urinary Incontinence System successfully passed all testing.

Biocompatibility Safety	The Host shell (ABS material) and Membrane Touch Switch (PET material) of the Urinary Incontinence System(P3-9632E1 and P3-9632E2) are respectively identical with the enclosure (ABS) and LCD cover (PET) of Combo Electrical Stimulation (P0-9612) as it was approved in [K130691,12/20/2013] in formulation, processing, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).
Electrical Safety	Finecure Urinary Incontinence System were tested in accordance with applicable clause of *IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), Medical electrical equipment –Part 1:General requirements for basic safety and essential performance.* Test results indicated that the Urinary Incontinence System comply with the applicable clauses of the Standards.
Electromagnetic Compatibility Testing	Finecure Urinary Incontinence System were tested in accordance with applicable clause of *IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.* Test results indicated that the Urinary Incontinence System comply with the applicable clauses of the Standards.
Home healthcare environment Testing	Finecure Urinary Incontinence System were tested in accordance with applicable clause of *IEC 60601-1-11: 2010 MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.* Test results indicated that the Urinary Incontinence System comply with the applicable clauses of the Standards.

Bench testing	The bench test had been conducted on Urinary Incontinence System, the test results indicated that the device meet design requirements.
Software verification and validation	The software verification and validation was performed on Urinary Incontinence System, the test results indicated that the Urinary Incontinence System meet the requirements of design.
Non-Clinical Summary	Non-clinical tests consist of Electrical safety (IEC 60601-1), EMC(IEC 60601-1-2), Performance (IEC 60601-2-10), safety in the home healthcare environment (IEC 60601-1-11) and bench test (manufacturer specification), the test results show that the proposed device complied with the requirements of standards aforesaid. The materials contacting with body is identical with the materials used in Combo Electrical Stimulation (P0-9612) as it was approved in [K130691,12/20/2013], the test for compatibility was not conducted.

Conclusion

Based on the comparison and performance testing, the proposed device is Substantially Equivalent (SE) to the predicate device.